510 (k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92

Date: January 17, 2012

1. Contact:

	Company
Name	Jeil Medical Corporation
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Fax	+82 2 850-3525
Contact	Mr. Ron Arkin
Internet	ronarkin@arkinconsulting.com

2. Device:
   - Proprietary Name – LeForte Neuro System Bone Plate & Screw
   - Common Name – Bone Plate, Bone Screw
   - Classification Name – Plate, Cranioplasty, Preformed, Alterable
     Fastener, Plate, Cranioplasty

3. Predicate Devices:
   - Jeil Medical Corporation/ LeForte Neuro System Bone Plate / K091679
   - Jeil Medical Corporation/ LeForte Neuro System Bone Plate / K103778
   - Jeil Medical Corporation/ LeForte Neuro System Bone Screw / K091686

4. Regulatory Classifications, Product Code:
   21CFR882.5320, GWO, Class II
   21CFR882.5360, HBW, Class II

5. Performance Standards:
   No applicable performance standards have been issued under section 514 or under section 513(b) of the Food, Drug and Cosmetic Act.

6. Description:
   The LeForte Neuro System Bone Plate & Screw is made of pure Titanium (ASTM F67) and Titanium Alloy (ASTM F136). It is intended for use in selective trauma of the cranial skeleton, cranial surgery and reconstructive procedures.

7. Indications for Use:
   This device is intended for use in selective trauma of the cranial skeleton, cranial surgery and reconstructive procedures.

8. Contraindications:
   - Not for use in cases of active or suspected infection or in patients previously sensitized to Titanium.
   - Not for use in patients exhibiting disorders which would cause the patient to ignore the limitations of rigid fixation plate and screw implants.

9. Potential Adverse Affects:
   - Poor bone formulation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device or premature loss of fixation with the bone, leading to nonunion.
   - Nonunion or delayed union which may lead to breakage of the implant
   - Migration, bending, fracture or loosening of the implant
   - Metal sensitivity, or allergic reaction to foreign body
   - Decrease in bone density due to stress shielding
   - Pain, discomfort, or abnormal sensation due to the presence of the device
   - Increased fibrous tissue response around the fracture site and/or the implant
   - Necrosis of bone
   - Inadequate healing

   Apart from these adverse effects there are always possible complications of any surgical procedure such as but not limited to, infection, nerve damage and pain which may not be related to the implant.

10. Predicate comparison:
    The LeForte Neuro System Bone Plate & Screw has the same device characteristics, material, design and intended use as the predicate devices identified.

Parameter	**LeForte Neuro System Bone Plate & Screw Jeil Medical Corporation**	**LeForte Neuro System Bone Plate, LeForte Neuro System Bone Screw Jeil Medical Corporation**
K#	Modified ✓	K091679, K103778, K091686
Indications for use	This device is intended for use in selective trauma of the cranial skeleton, cranial surgery and reconstructive procedures.	
Shape	The same models with the addition of Triangular shapes	Mesh, Straight, Y, Curved, Square, Quad, X, Calvarium, Double Y, Gap, Bur hole, Mesh_MA, Mesh_MB, Mesh_MC, Mesh_MD, NF Auto Screw-Micro, NF Auto Screw-Mid
Dimensional	Plate thickness 0.3~0.6m Screw Outer diameter 1.4~1.9mm Screw Length 2.2~5.0mm	Plate thickness 0.3~0.6m Screw Outer diameter 1.4~1.9mm Screw Length 3.0~5.0mm
Material	Plate - Titanium ASTM F67 Grade1, 2, 3 Screw – Titanium Alloy ASTM F136	

LeForte Neuro System Bone Plate & Screw

Parameter	LeForte Neuro System Bone Plate & Screw Jeil Medical Corporation	LeForte Neuro System Bone Plate, LeForte Neuro System Bone Screw Jeil Medical Corporation
Surface	Plate: Anodizing Screw: N/A	
Sterilization	Non sterile	
Single use	Yes	
Packaging	Vial, PA+PE film sealing	

11. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Jeil Medical Corporation Concludes that the LeForte Neuro System Bone Plate & Screw is safe and effective and substantially equivalent to the predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Jeil Medical Corporation
c/o Mr. Paul Sumner
Official Correspondent
Arkin Consulting Group LLC
1733 Canton Lane
Marietta, GA 30062

FEB 2 2 2012

Re: K112812
LeForte Neuro System Bone Plate & Screw
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed alterable cranioplasty plate
Regulatory Class: Class II
Product Code: GWO, GXR, HBW
Dated: January 19, 2012
Received: January 23, 2012

Dear Mr. Sumner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known)	**K112812**
Device Name	LeForte Neuro System Bone Plate & Screw
Indications for Use	This device is intended for use in selective trauma of the cranial skeleton, cranial surgery and reconstructive procedures.

Prescription Use ✓ (Per 21 CFR 801. Subpart D) OR Over-The-Counter Use_____ (21CFR801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K112812